REMARKS

Claims 1-17 and 19-27 are now pending in this application. Claims 7-10, 13, 16, 17 and 25-27 are withdrawn from consideration as being directed to a non-elected invention. Claims 1 and 12 are newly amended herein. Claim 18 is cancelled without prejudice or disclaimer of the cancelled subject matter. Applicants reserve the right to pursue any cancelled subject matter in one or more continuing or divisional applications. Claims 1-6, 11, 12, 14, 15 and 19-24 are under examination.

Support for the amendments to claim 1 are as follows:

Support for "different" in the phrase "different ligands" is found, for example, in paragraphs [0019, 0021], and elsewhere throughout the specification;

Support for "more than" in step (ii) is found, for example, in original claim 18, and elsewhere throughout the specification;

Step (iii) is amended to correctly recite antecedent basis from step (ii);

Support for the phrase "dissociated partially or completely" in step (iv) is found, for example, in paragraph [0029], and elsewhere throughout the specification; and,

Support for the phrase "wherein the activity assayed is not solely binding" in step (iv) is found, for example, in paragraphs [0007, 0033, 0034], and elsewhere throughout the specification.

The amendments to step (vi) are grammatical in nature.

Support for the amendments to claim 12 are found, for example, in paragraph [0007], and elsewhere throughout the specification.

The amendments are not believed to add new matter and entry is respectfully requested.

A. INTERVIEW SUMMARY

Applicants thank Examiner Steele and Primary Examiner Shibuya for the personal interview held at the Patent and Trademark Office (PTO) on March 20, 2007 with the undersigned and an inventor, Dr. Julia Lathrop. During the interview, the language of claim 1 was discussed in detail. The differences between the claim language and prior art documents Lam and Todaro were discussed. Claim language potentially overcoming the rejections was discussed. The amendments to the claims reflect, in part, the discussion held with the Examiners Steele and Shibuya during the interview.

B. ELECTION/RESTRICTION

At page 2 of the Office Action, the Office has maintained the restriction and species election requirement. Applicants note that in addition to claims 25-27, claims 7-10, 13, 16 and 17 are also withdrawn from consideration. The Office is reminded that according to PTO procedures set forth in the MPEP § 803.02 (August 2006), the Office will, following election, fully examine the Markush-type claim with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. Newly amended claim 1, the sole independent claim, is believed to be in condition for allowance. Thus, dependent claims 2, 4, 6, 11 and 15 should be examined in their entirety.

As the Office is aware, claims dependent from an allowable claim are allowable by virtue of dependency as long as the claims meet the requirements for patentability. Claims 7-10, 13, 16, 17 and 25-27, dependent from claim 1, and currently withdrawn from examination, are thus allowable.

The Office is respectfully requested to examine the remaining species in claims 2, 4, 6, 11 and 15 and rejoin claims 7-10, 13, 16, 17 and 25-27.

C. REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

At page 2 of the Office Action, claim 1 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. The rejection is respectfully traversed. Claim 1 is newly amended herein.

Claim 1, step (iv) is allegedly indefinite because it is not clear if the assayed entity is unbound or bound to the ligand-support complex at the time of assay. Without acquiescing to the propriety of the rejection, claim 1 is newly amended herein to recite the entity may be dissociated partially or completely from the entity-ligand-support complex isolated in previous step (iii). Support for the amendment is discussed, above.

The amendments to claim 1 are believed to overcome the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

II. REJECTION UNDER 35 U.S.C. § 102(B) OVER TODARO

At page 3 of the Office Action, claims 1-6, 11, 12, 14, 15, 18 and 20 remain rejected under 35 U.S.C. §102(b) as allegedly anticipated by Todaro (U.S. Patent No. 4,816,561). The rejection is respectfully traversed. Claim 1 is newly amended herein; claim 18 is newly cancelled.

The rejection over Todaro is fatally defective for at least the following reasons: Todaro fails to teach each element of the invention *as claimed*, and, the invention of Todaro is NOT identical to the invention claimed.

A. TODARO FAILS TO TEACH EACH ELEMENT OF THE CLAIMS

The claimed invention differs from Todaro in at least 3 aspects: Claim 1 (step i) employs a plurality of different ligands; claim 1 (step ii) employs a mixture of a plurality of entities to form more than one entity-ligand-support complex; and, claim 1 (step iii) separates more than one entity-ligand support complex.

For example, step (i) of amended claim 1 recites a plurality of different ligands. In contrast, Todaro employs a known ligand which is, *inter alia,* an oligopeptide derived from TGF polypeptides. By employing a known ligand derived from TGF, Todaro

differs from claim 1 which recites "a plurality of different ligands." A known ligand derived from TGF does not anticipate a plurality of different, unspecified, ligands.

In a different example, step (ii) of amended claim 1 recites "... at least one entity to bind to at least one ligand-support complex, thereby forming more than one entity-ligand-support complex." In the claimed invention, the entities bound to the ligand-support complexes are from the mixture of entities and the characteristics of any particular bound entity are unknown until assayed. The ligand-support-complexes, each complex comprising a different ligand, bind a different entity from the mixture of entities. In contrast, Todaro intentionally employs a known ligand, a TGF derived peptide, to intentionally bind cellular growth factor receptors with an explicit purpose of identifying a peptide useful in the treatment of diseases related to TGF. See, for example, Todaro, column 3, lines 5-29.

There is yet another example of the differences between the claimed invention and Todaro. Amended claim 1 step (iii) recites in part "separating more than one entity-ligand-support complex from the unbound entities." Because a plurality of different ligands bind different entities from a mixture of entities, different combinations of entity-ligand-support complexes result. The separation in step (iii) of more than one entity-ligand-support complex from the unbound entities results in the separation of a small subset of the different combinations formed in step (ii). Unlike Todaro, who purifies a single type of molecule by employing a TGF-derived peptide (ligand) to bind a single type of entity (i.e., cell growth receptors) from body fluids, practice of the claimed method does not purify a single entity.

As the Office is aware, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Thus, Todaro, failing to teach each and every element of the claim, does not anticipate independent claim 1, or claims 2-6, 11, 12, 14, 15 and 20, dependent therefrom.

B. TODARO FAILS TO SHOW THE IDENTICAL INVENTION

As the Office is aware, "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Todaro fails to show the identical invention recited in claim 1 and claims dependent therefrom. Claim 1 recites a method for screening active entities. The claimed method for screening comprises, *inter alia*, providing a plurality of different ligands, a mixture comprising a plurality of entities, separating more than one entity-ligand-support complex from the unbound entities and then assaying the activity of the partially dissociated or completely dissociated entity. The activity of the entity is detected and the entity-ligand-support complex that bound the entity that exhibited the detected activity is then selected.

Todaro, in contrast, is directed to a method for isolating and purifying TGF polypeptides. Todaro accomplishes purification of the TGF polypeptides by a method comprising, *inter alia*, dialysis against acetic acid, gel permeation chromatography, reverse phase HPLC and lyophilization in order to obtain the TGF polypeptide as a single peak in the state of a homogenous polypeptide. Todaro employs methods, procedures and techniques which differ from the those of the claimed invention. Thus, Todaro does not teach an invention identical to the invention claimed, and as such, does not anticipate claim 1, or claims dependent therefrom.

The Office arguments can be summarized as follows: Todaro teaches, *inter alia,* "a process for isolating homogenous transforming growth factor polypeptides from less pure aqueous solutions...including body fluids and aqueous medium." Office action at 5. However, claim 1 recites a "method of screening a mixture for active entities." In contrast to the claimed screening method for active entities using a plurality of different ligands and a mixture of uncharacterized entities, Todaro is directed to purification of TGF derived peptides employed to specifically bind only to cellular growth factor receptors. See, for example, the abstract, stating "..as well as a process for isolating the TGF polypeptides from both human and murine cell lines in homogenous form."

Methods of screening are different from methods of purification. Todaro does not teach screening methods and thus does not teach that particular claim element, or show the identical invention. Contrary to the position of the Office, claim 1 is not anticipated by "methods of purification."

In view of the amendments to the claims and arguments above, the rejection is believed to be overcome. Reconsideration and withdrawal of the rejection is respectfully requested.

III. REJECTION UNDER 35 U.S.C. § 102(B) OVER LAM

At page 5 of the Office Action, the Office maintained the rejection of claims 1-6, 11, 12, 14, 15 and 18-24 as allegedly anticipated by Lam (U.S. Patent No. 5,510,240). The rejection is respectfully traversed. Claim 1 is newly amended and claim 18 is newly cancelled herein.

The rejection over Lam is fatally defective for at least the following reasons: Lam fails to teach each and every element of the invention *as claimed*, and, the invention of Lam is NOT identical to the invention claimed.

A. LAM FAILS TO TEACH EACH ELEMENT OF THE CLAIMS

The claimed invention differs from Lam in at least 3 aspects: claim 1 (step iv) recites "assaying the activity of the entity;" claim 1 (step iv) recites "wherein the activity assayed is not solely binding of the entity to the ligand-support complexes;" and, claim 1 (step vi) recites "selecting ....the entity-ligand-support complex that bound the entity that exhibited the detected activity."

Lam is directed to, *inter alia*, methods of identifying bio-oligomers from a library wherein the bio-oligomers demonstrate desired characteristics such as binding, bioactivity and catalytic activity. In Lam, the bio-oligomers are attached to solid phase supports and bind to acceptor molecules. Thus, the bio-oligomers of Lam correspond to the ligands of the claimed invention in linking the entity (i.e., acceptor molecule) to the support.

Lam differs from claim 1 (step iv) because Lam assays the activity of the ligand, not the acceptor molecule as required by claim 1. See, for example, Lam, column 2, lines 35-36, stating the bio-oligomers may catalyze a chemical reaction; see also lines 32-35, stating the bio-oligomers characterize ligands capable of binding to acceptor molecules or mediating a biological activity of interest. Lam simply does not teach assay of the activity of the **entity**, a recited and required element of claim 1 (step iv), because Lam employs a predetermined entity (acceptor molecule) having a predetermined activity.

Lam also does not teach or suggest "assaying the activity of the entity wherein the entity may be dissociated partially or completely from an entity-ligand-support complex separated in step (iii))..." a required element of claim 1 (step iv). Lam assays the binding of the bio-oligomer to the acceptor molecule and assays the bio-oligomer for an activity of interest, whereas in contrast, the claimed invention assays the binding and assays the activity of the entity dissociated partially or completely from the entity-ligand-support complex.

In another example, Claim 1 (step vi) recites "selecting ....the entity-ligand-support complex that bound the entity that exhibited the detected activity." In Lam, each bio-oligomer species to which the acceptor molecule binds is found on a single solid phase support so that the support, and thus the bio-oligomer, can be readily identified and isolated (column 17, lines 57-60). Lam thus differs from the claim element because Lam selects the acceptor-bio-oligomer-support based on the activity of the bio-oligomer, not on the basis of the entity that exhibited the detected activity as required in claim 1 (step vi) of the claimed invention.

As the Office is aware, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Thus, Lam, failing to teach each and every element of claim 1, does not anticipate claim 1, or claims 2-6, 11, 12, 14, 15 and 19-24, dependent therefrom.

B. LAM FAILS TO SHOW THE IDENTICAL INVENTION

As the Office is aware, "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Lam's invention is not identical to the method claimed in newly amended claim 1. Lam's invention is directed, *inter alia*, to identifying and characterizing ligands to predetermined acceptor molecules (see, for example, column 17, lines 35-39). Lam's method assays the activity of the ligand (bio-oligomer) once binding to the appropriate acceptor molecule is detected or determined. Unlike the presently claimed invention, Lam is not concerned with the activity of the acceptor molecule once a bio-oligomer of interest or having the activity of interest is identified. Because Lam fails to show an invention identical to that as contained in claim 1, and claims dependent therefrom, the rejection is legally defective and improper.

The Office arguments concerning Lam are summarized as follows: Lam teaches bio-oligomers that bind various acceptor molecules or substrate molecules, panning with both non-bio-oligomeric specific proteins/cells and bio-oligomer specific proteins/cells, and separating, for example, support-bio-oligomer acceptor substrates from support bio-oligomers. Office Action at 8. However, the Office fails to consider the claim as a whole. Contrary to Office arguments, Lam does not assay the activity of entity, wherein the activity assayed is not solely binding of the entity to the ligand-support complex as recited in claim 1 step (iv) or the invention as claimed, for example, in the sequence of claim 1 steps (ii), (iii) and (iv).

In view of the amendments to the claims and arguments above, the rejection is believed to be overcome. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully submit that the present application is in condition for examination on the merits. If the Examiner

believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

In the event any variance exists between the amount of fees paid upon filing this document and the Patent Office charges for filing this document, including any fees required under 37 CFR § 1.136 for any necessary extension of time to make the filing of this document timely, please charge or credit the difference to Deposit Account No. 13-2725. Further, if these papers are not considered timely filed, then a request is hereby made under 37 CFR § 1.136 for the necessary extension of time.

Respectfully submitted,

MERCHANT & GOULD P.C.

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